



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Re: Docket No. 98P-0869/CP2

Dear Sirs:

I am writing to inform you that the Food and Drug Administration (FDA) is not yet able to issue a response to your citizen petition dated December 14, 1998, in which you request that the FDA take certain actions regarding pediatric exclusivity.

FDA has been unable to issue a response to your petition because of ongoing litigation that was only recently completed when the parties stipulated to dismissal of the action on May 14, 1999. You might wish to consider withdrawing your petition in light of the court's decision in that case on a Motion for Preliminary Injunction (copy enclosed). This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). Should you not withdraw the petition, we will respond to your petition as soon as possible now that the litigation has been completed.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center of Drug Evaluation and Research

Enclosure

98P-0869

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